UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,522	02/20/2004	Roy Lurie	MWS-109	7481

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EXAMINER
WHALEY, PABLO S

ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
Office Action Summary	10/783,522	LURIE, ROY
	Examiner	Art Unit
	Pablo Whaley	1631

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). ·
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>02 February 2007</u>.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-50</u> is/are pending in the application.

    4a) Of the above claim(s) <u>37-50</u> is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-36</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

U.S. Patent and Trademark Office

PTOL-326 (Rev. 08-06)   Office Action Summary   Part of Paper No./Mail Date 20070418 .

DETAILED ACTION

Applicants' response, filed 02/02/2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims 1-36 are herein under examination. This application contains claims 37-50 drawn to an invention nonelected with traverse in the response filed 7/31/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

INFORMALITIES

The specification has been amended to remove embedded hyperlinks and/or other form of browser-executable code on page 20, and elsewhere, and capitalize Trademark names. The specification is now acceptable.

NEW MATTER

Claims 1-11 and 28-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 1 and 28 have been amended to recite "<u>instructions</u> comprising: <u>instructions for</u> a simulation engine..." and "<u>instructions for</u> an analysis environment." In the response filed 02/02/2007, applicant points to originally filed claims 1, 12, 22, and 28 as support of the newly recited limitations. However, the Examiner has not found support for these limitations in the specification, and these limitations are not present within the scope of the above claims as filed. For example, originally filed claim 22 recites a computer-readable program means for generating an expected result, however this is not support for "instructions for a simulation engine generating an expected result." As the newly recited limitations are not supported by the originally filed claims or disclosure, the claims are rejected for reciting new matter. This rejection is necessitated by amendment.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 and 28-36 remain rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter, as set forth in the Office action mailed 10/02/2006.

Applicant's arguments, filed 2/02/2007, that the instant claims now recite a concrete, tangible, and useful result in view of the amendment to claims 1 and 28, which now recite a medium holding instructions, is not deemed to be persuasive. This rejection is maintained for the reasons set forth below.

Claims 1-11 and 28-36 are now directed to a medium holding instructions executable in a computing device comprising instructions for a simulation engine and instructions for an analysis environment in communication with said simulation engine. Thus, the instant claims are generally directed to a machine-readable storage system comprising a program containing a set of instructions (i.e. process). A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)].

It is noted that while claims 1 and 28 recite instructions, these instructions are not active method steps. Thus, the instant claims comprise steps that do not result in a physical transformation of matter, as the claimed method steps are not limited to physical steps (i.e. steps done by a user), and therefore encompass non-physical method steps that may be practiced inside of a computer (i.e. *in-silico*). Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claims ultimately result in "instructions for an analysis

environment" and thus lack a tangible result as nothing is communicated to a user such that it is

useful to one skilled in the art. For these reasons, the instant claims are not statutory.

This rejection could be overcome by amending the claims to recite a computer readable

medium comprising a program containing instructions, wherein the program result is "displayed"

or "output" (e.g. output to a user, a display, a memory, or another computer, etc.), or by

amending the claims to include a step of a physical transformation of matter (e.g. assay). For an

updated discussion of statutory considerations with regard to non-functional descriptive material

and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the

MPEP 2106, Section IV.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and
> distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 22-36 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

Claims 1, 22, and 28 now recite the limitation "experimental results generated by an in

situ experiment conducted on a experimental device" in the preamble. It is unclear if applicant

intends the functional limitation "generated by an in situ experiment..." to be an actual method

step, a further limitation of the claimed method, or otherwise. Applicant's amendments have not

clarified this issue. Clarification is again requested. Claims which are directly or indirectly

dependent from claims 1, 22, and 28 are also included as rejected herein due to said dependence. *This rejection is maintained.*

Claims 5, 16, and 32 recite the limitation "modeling environment." As the specification does not define or fully and completely describe "environment," it is unclear as to the metes and bounds intended by applicant for the claimed "modeling environment." Applicant's amendments have not clarified this issue. Clarification is again requested. *This rejection is maintained.*

Claims 1 and 28 now recite "instructions for a simulation engine generating an expected result." It is unclear whether said instructions for simulation engine are intended to control said generating, or something else. Clarification is requested. *This rejection is necessitated by amendment.*

Claims 1 and 28 now recite "instructions for an analysis environment..., said analysis environment gathering data...and comparing the expected result...". It is unclear whether said instructions for an analysis environment are intended to control said gathering and comparing, or something else. Clarification is requested. *This rejection is necessitated by amendment.*

Claim 11 now recites the limitation "wherein said analysis environment gathers data from a microarray." As parent claim 1 is directed to a medium holding instructions, it is unclear if applicant intends for said "gathers data from a microarray" to be an actual method step, a functional limitation of said analysis environment, or otherwise. Clarification is requested. *This rejection is necessitated by amendment.*

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis

for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 22, 23, 25-27, 28-30, and 32-36 remain rejected under 35 U.S.C. 102 (b) as being

anticipated by Goryanin et al. (Bioinformatics, 1999, Vol. 15, No. 9, p.749-758), as set forth in

the Office Action mailed 10/02/2006.

Applicant's arguments, filed 2/2/2007, that Goryanin et al. fail to disclose the features

where (i) experimental data is gathered from an in situ experiment conducted on an

experimental device, and (ii) comparing the expected result to data gathered from the

experimental device are not persuasive for the following reasons. This rejection is therefore

maintained.

Regarding (i): Claims 1 and 28 are now both directed to a medium holding instructions

executable in a computing device "for modifying a model in response to experimental data is

generated by an in situ experiment conducted on an experimental device", as recited in the preamble of claims 1 and 28. Thus the feature argued by applicant is directed to an intended use, as claims 1 and 28 do not recite any instructions or active method steps directed to gathering data from an in situ experiment or conducting an experiment on an experimental device. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As set forth in the previous office action, mailed 10/2/2006, Goryanin et al. clearly teach a computer-readable program (i.e. medium holding instruction executable in a computer) called DBsolve 5.00 for carrying out instructions. Goryanin et al. also teach "simulation" of biological data (i.e. electronic experiments) [p.750, Col. 1, ¶ 3], thus the computer itself is the experimental device.

Regarding (ii): Goryanin et al. also teach a program for optimizing (i.e. modifying) a biological model using experimental data, wherein observed data (i.e. expected data) is compared with model simulated data [Fig. 1] and [p.753, Col. 1, ¶ 2], which is a teaching for comparing the expected result to data gathered from the experimental device. It is noted that the nature of experimental data (i.e. in situ data), per se, has no restrictive effect on the claimed medium. Therefore, the Examiner maintains that he has broadly and reasonably interpreted the above limitations (i) and (ii) to encompass the teachings of Goryanin et al.

Regarding amended claim 4, Goryanin et al. generates an optimized curve when the difference between experimental data and theoretical data is calculated according to an absolute value (i.e. threshold) [p.755, Col. 1, ¶ 1]. As the specification has not provided a limiting definition for the term "event signal", as in amended claim 4, the Examiner has broadly interpreted the teaching of Goryanin to encompass generating an event signal as in instant

claim 4. For these reasons and those set forth above, the Examiner maintains that Goryanin et

al. indeed teach all of the limitations of claims 1-9, 22, 23, 25-27, 28-30, and 32-36.

Claims 1-2 and 10 remain rejected under 35 U.S.C. 102 (b) as being anticipated by DelaFuente

et al. (Proceedings of the Second International Conference on Systems Biology, Pasadena,

California, 2001, p. 213-221), as set forth office action mailed 10/02/2006.

Applicant's arguments, filed 2/2/2007, that DelaFuente et al. fail to disclose an "analysis

environment in communication with said simulation engine, said analysis environment gathering

data from said experimental device and comparing the expected result to data gathered from

said device" is not persuasive for the following reasons. This rejection is therefore maintained.

Claim 1 is now directed to a medium holding instructions executable in a computing

device, comprising instructions for an analysis environment that is functionally limited to

gathering data from said experimental device and comparing the expected result to data

gathered from said device. DelaFuente et al. teach computer simulations using gene expression

data, wherein gene expression data is obtained from microarray experiments [p. 214, Section 2,

Method] and [p.215, Col. 2, ¶ 1], which equates to data from an experimental device, as in claim

1. DelaFuente et al. also teach a software analysis environment (i.e. analysis environment) that

compares theoretical data and regulatory strength values based on experimental microarray

data, and a computer model (i.e. simulation engine) that takes in data and generates expected

results [Table 1] and [p.216, Col. 2, ¶ 2]. Therefore, the Examiner maintains that he has broadly

and reasonably interpreted the limitation of an "analysis environment in communication with said

simulation engine, said analysis environment gathering data from said experimental device and

comparing the expected result to data gathered from said device" to encompass the teachings

of DelaFuente et al. It is noted that the nature of experimental data, per se, has no restrictive effect on the claimed analysis environment. For these reasons and those set forth above, the Examiner maintains that DelaFuente et al. indeed teach all of the limitations of claims 1-2 and 10.

Claims 12-19 and 21 remain rejected under 35 U.S.C. 102 (e) as being anticipated by Potts et al. (US Pat. No. 6,882,940; Filed Aug. 10, 2001), as set forth Office action mailed 10/02/2006.

Applicant's arguments, filed 2/2/2007, that Potts et al. fail to disclose "comparing, by an analysis environment, the generated expected result to data gathered from said experimental device" is not persuasive for the following reasons. This rejection is therefore maintained.

Claim 12 is now directed to a medium holding instructions executable in a computing device "for modifying a model in response to experimental data is generated by an in situ experiment conducted on an experimental device", as recited in the preamble of claim 12. Thus the features argued by applicant are directed to an intended use. However, Potts et al. teach microprocessors comprising programming (i.e. analysis environment) for comparing skin conductance readings (i.e. in situ experimental data) with threshold values (i.e. expected results) [Reference claims 1 and 25], as in instant claim 12. Potts et al. also teach an alert signal (i.e. event signal) generated when glucose amount is outside of the predetermined range of values [Co. 7, lines 20-23], as in instant claim 15. Potts et al. also teach a prediction system (i.e. modeling environment) allowing for user-settable threshold levels [Col. 13, lines 20-25], which is a teaching for modifying the model based on optimization means (i.e. thresholding), as in claim 12. Therefore, the Examiner maintains that he has broadly and reasonably interpreted the "comparing, by an analysis environment" limitation to encompass the teachings of Potts et al.

For these reasons and those set forth above, the Examiner maintains that Potts et al. indeed

teach all of the limitations of claims 12-19 and 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 10-14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being made obvious by

DelaFuente et al. (Proceedings of the Second International Conference on Systems Biology,

Pasadena, California, 2001, p. 213-221), as applied to claims 1-2 and 10, above, in view of

Bubendorf et al. (Journal of Pathology, 2001, Vol. 195, p.72-79). *This rejection is necessitated

by amendment.*

Applicant has amended claim 11 to require data from a "gene chip." Applicant's arguments

that DelaFuente et al. and Bubendorf et al., alone or in combination, do not suggest gathering

data relating to the experimental and comparing, by analysis environment, the generated

expected result to data gathered from said experiment are not persuasive for the following reasons.

It is noted that the examiner maintains that DelaFuente et al. do, in fact, teach the limitations of claims 1-2 and 10 for the reasons set forth above. As the examiner maintains that DelaFuente et al. teach the limitations of claims 1-2 and 10, as set forth in the previous office action and maintained above, he also maintains that DelaFuente et al. combined with Bubendorf et al. make obvious claims 12, 13, 14, 20, and 21 for the reasons and motivation previously set forth in the Office action mailed 10/02/2006.

As set forth Office action mailed 10/02/2006, DelaFuente et al. teach a method for reverse engineering gene regulatory networks from microarray gene expression data using a computer system [Abstract], as set forth above. DelaFuente et al. also teach gene expression data obtained from microarrays (i.e. gene chips) [p. 214, Section 2, Method], as in claim 11, and methods of displaying data, as set forth above and recited in claims 13 and 14.

DelaFuente et al. do not specifically teach the use of in situ experimentation, as recited in claims 12 and 20. However, DelaFuente et al. suggest that their method is very suitable to be applied to microarray technologies.

Bubendorf et al. teach a method of high-throughput in situ experimentation using tissue microarrays (TMA) technology [Abstract]. Bubendorf et al. also teach the display of in situ TMA experiments in patient samples [Fig. 5] and related data sets [Table 1], as in instant claims 12 and 20.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention use the gene regulatory network model of DelaFuente et al. with the TMA data sets taught by Bubendorf et al, where the motivation would have been to significant accelerate tumor research using high-throughput in situ technologies [Bubendorf et al., Abstract], resulting

in the practice of the instant claimed invention with a reasonable expectation of success. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the data sets of Bubendorf et al. with the model of DelaFuente et al. as both teach microarray data sets and analysis.

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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